Remarks

Claims 1 - 50 are pending in the application, and all claims currently stand rejected. Reconsideration is requested in view of the following remarks.

Response to section 102(e) rejection

Claims 1, 2, 19, 22, 33, 36, 39, 40 and 41 are rejected under 35 U.S.C. §102(e) or, in the alternative, under 35 U.S.C. § 103(a) over WO 00/54943 of Khalifah et al. (Khalifah). Applicant respectfully traverses the rejection. As will be explained below, Khalifah is not a competent prior art reference to the present application.

On November 29, 2000, amendments to 35 U.S.C. §§102(e) and 374 relating to the prior art effect of published PCT applications took effect. These amendments, deriving from the American Inventors Protection Act (AIPA), provide[1]:

> §374: The publication under the treaty defined in section 351(a) of this title [the PCT] of an international application designating the United States shall confer the same rights and shall have the same effect under this title as an application for patent published under section 122(b), except as provided in sections 102(e) and 154(b) of this title.

> §102: A person shall be entitled to a patent unless:
> (e)the invention was described in --
> (1) an application for patent published under section 122(b) by another filed in the United States before the invention by the applicant for patent, except that an international application defined in the treaty defined in section 351(a) of this title [a PCT application] shall have the effect under this subsection of a national application published under section 122(b) only if the [PCT] application designating the United States was published under Article 21(2)(a) of the [PCT] in the English language.

[1]see http://www.uspto.gov/web/offices/dcom/olia/35amend2.pdf

However, §4508[2] in Subtitle E of the AIPA provides in relevant part (emphasis added):

> Sections 4502 through 4507[3], and the amendments made by such sections, shall take effect on [November 29, 2000] and shall apply to all applications filed under section 111 of title 35, United States Code, **on or after that date**, and all applications complying with section 371 of title 35, United States Code, that resulted from international applications filed **on or after that date**.

The effect of the 35 U.S.C. §§ 102(e) and 374 amendments, in light of AIPA §4508, is to allow compliant PCT applications to be 102(e) prior art to US ordinary or US national stage applications **filed on or after November 29, 2000**. Applications filed before November 29, 2000 are subject to the "old" 102(e), which allowed only issued US patents to be prior art under that section. This is consistent with the view of the USPTO as reported by Maria Eliseeva in "Ariadne's Thread in the AIPA Labyrinth," Intellectual Property Today (Dec. 2000), pgs. 20 - 24, copy enclosed. See especially pg. 20, col. 3 and the section entitled "Prior Art Effect of Published PCT Applications" on pg. 22, col. 3 of Ms. Eliseeva's article.

The present application was filed **before** November 29, 2000, and thus is subject to the "old" 102(e). Because Khalifah is not an issued US patent, it cannot properly be applied to the present application as a 102(e) prior art reference. Khalifah may therefore only qualify as a reference under 102(a) or (b), based solely on its international publication date. Khalifah's international publication date is October 12, 2000. The present application has an international filing date of August 6, 1998 and a priority date of August 7, 1997, both of which are prior to the international publication date of Khalifah. Thus, Khalifah does not qualify as 102(a) or (b) prior art to the present application. Because Khalifah cannot be used to sustain a rejection under 35 U.S.C. 102(e), (a) or (b), the anticipation rejection over this reference is improper and should be withdrawn. Be-

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[2] see http://www.uspto.gov/web/offices/com/speeches/s1948gb1.pdf

[3]The amendments to 35 U.S.C. §§102(e) and 374 are contained in AIPA §§4505 and 4507, respectively; see http://www.uspto.gov/web/offices/com/speeches/s1948gb1.pdf

cause this document is not a competent prior art reference, the 35 U.S.C. 103(a) rejection over Khalifah is also improper and should be withdrawn.

Examiner discusses (though does not specifically apply) Hudson with respect to the rejected claims, apparently to establish that vitamin B_1 and B_6 derivatives are "advanced glycation end-product" (AGE) inhibitors. Examiner then states that "[i]t is well known in the art that advanced glycation end-products accumulate in the tissues of patients undergoing dialysis and that these advanced glycation end-products are associated with several adverse side effects." See pg. 2 of the Detailed Action. Examiner provides no documentation in support of this latter statement beyond what may be disclosed in Khalifah; however, Applicant has shown above that Khalifah is not a prior art reference to the present application.

In any case, the relevance of AGE inhibitors to the present claims is not specifically discussed by Examiner. The rejected claims are directed to methods of preventing or correcting vitamin deficiencies in dialysis patients with dialysis solutions containing certain water-soluble vitamins, and to the dialysis solutions themselves. Hudson does not disclose or suggest that AGE-related conditions are due to vitamin deficiencies caused by dialysis, despite the fact that vitamin B_1 and B_6 derivatives may be AGE inhibitors. In fact, Hudson states that AGE-inhibition "has utility in the areas of, for example, food spoilage, animal protein aging, and personal hygiene such a combating the browning of teeth." See Hudson, col. 3, lns. 19 - 21. Prevention of AGE-related effects due to dialysis-induced vitamin deficiency with a vitamin-enriched dialysis solution is not mentioned in Hudson. Any attempt to draw a connection between the teachings of Hudson and the present invention are therefore the product of impermissible hindsight, and/or the improper use of Khalifah as a reference. Thus, Hudson cannot support an anticipation or obviousness rejection of the present claims.

Response to section 103(a) rejections relying on Khalifah

All the obviousness rejections discussed below depend on either Khalifah alone or on Khalifah as the primary reference in combination with one or more secondary references. Khalifah is not a competent reference for this application. None of the sec-

ondary references relied on by Examiner standing alone can support an obviousness rejection. Thus, all obviousness rejections including Khalifah as a reference must be withdrawn. The specific rejections are discussed in more detail below.

Claims 3 - 12, 23, 24, 26 and 27 are rejected under 35 U.S.C. 103(a) as allegedly rendered obvious over Khalifah. Hudson is again discussed, but not specifically applied, with regard to the rejected claims.

Khalifah is not a competent reference. The relationship of Hudson to the present invention is discussed above. Furthermore, Examiner admits on pg. 3, paragraph 4 of the Detailed Action that Hudson "does not specifically disclose the use of physiological or supraphysiological amounts of Vitamin B_1 or B_6 to [*sic*] dialysis solution." Thus, Hudson does not disclose or suggest methods of preventing or correcting vitamin deficiencies in a dialysis patient with dialysis solutions comprising the claimed water-soluble vitamins.

Claims 16 - 18, 20, 31 - 34, 38 and 41 are rejected as allegedly rendered obvious by Khalifah in view of US Pat. No. 4,237,167 of Cavazza et al. (Cavazza). These claims are directed to methods of preventing or correcting vitamin deficiencies in dialysis patients with a dialysis solution comprising combinations of the listed water-soluble vitamins and carnitine, and to the dialysate solution itself.

Cavazza discloses the use of acyl carnitine in dialysis solutions to supplement depleted carnitine in dialysis patients. There is no disclosure or suggestion in Cavazza of including folic acid, vitamin B6, thiamine, vitamin C and/or vitamin B12 in the dialysis solution. Khalifah is not a competent reference, and thus cannot provide a teaching to include these water-soluble vitamins in a dialysis solution containing carnitine.

Claims 13 - 15, 29 - 30 and 37 are rejected as allegedly rendered obvious by Khalifah in view of Pru et al. (1985) Nephron 39: 112-116 (Pru). These claims are directed to methods of correcting or preventing vitamin deficiency with a dialysis solution comprising combinations of the listed water-soluble vitamins and vitamin C, and to the dialysis solution itself. Examiner admits that Pru does not disclose that vitamin B_1 or B_6 can be added to a dialysis solution together, but asserts that "dialysis patients are known" to have deficiencies in all three of these vitamins. No authority is given for this statement. Regardless, the mere recognition that dialysis patients may need vitamin B_1 or B_6 supplementation does

not establish that supplementation via dialysis of these and other water-soluble vitamins, in combination with vitamin C, would be effective. At best, this would be an invitation to *try* to solve the problem of vitamin deficiencies in dialysis patients. Khalifah, which is not a competent reference, of course cannot be used to provide the missing elements or provide the motivation to construct the rejected claims.

Claims 5 - 6, 11 - 12, 21, 25, 35, 43 and 48 - 50 are rejected as allegedly rendered obvious over Khalifah in view of Cavazza and Pru. These claims are directed to methods of correcting or preventing vitamin deficiency with a dialysis solution comprising the various water-soluble vitamins, either alone or in combination with vitamin C, carnitine or mineral supplements, and to a dialysis solution comprising folic acid, vitamin B_6, thiamine or vitamin B_{12}, vitamin C and carnitine. As discussed above, neither Pru nor Cavazza teach that water-soluble vitamins can or should be added to dialysis solutions. Furthermore, neither of these references discloses or suggests that vitamin C and carnitine may be mixed in a single dialysis solution. Khalifah is not a competent reference, and thus cannot provide the missing elements or the motivation to combine the teachings of Pru and Cavazza.

Because none of the obviousness rejections discussed above can be maintained without Khalifah, Applicant respectfully requests that these rejections be withdrawn.

Response to section 103(a) rejections relying on Allen and Trimbo

Claims 44 - 46 are rejected as allegedly rendered obvious by US Pat. No. 5,635,199 to Allen et al. (Allen). These claims are directed to vitamin *concentrate* solutions for use in a dialysate solution, comprising at least one of the listed water-soluble vitamins, or various combinations of these vitamins, vitamin C and carnitine. The word "concentrate" implies that the components in the claimed solutions are not ready-to-use, but must first be diluted. This is not an intended use, but a characteristic of "concentrates."

Allen discloses methods for oral or transdermal administration of *ready-to-use* vitamin preparations of folate and vitamins B_6 and B_{12}, for the treatment of conditions resulting from deficiencies in these vitamins. The vitamin preparations of Allen are not concentrated. There is also no teaching or suggestion in Allen that vitamin C or carnitine

may be included with the water-soluble vitamins in a concentrated solution. Thus, Allen would not suggest to one of ordinary skill in the art to make the concentrated solutions of claims 44 - 46, and the obviousness rejection over this reference should be withdrawn.

Claims 44 - 47 are rejected as allegedly rendered obvious over US Pat. No. 5,635,199 to Trimbo et al. (Trimbo). Claims 44 - 46 are discussed above. Claim 47 is directed to a vitamin concentrate solution comprising folic acid, vitamin B6, thiamine, vitamin B12, vitamin C, carnitine and pharmaceutically acceptable salts thereof. Trimbo discloses an oral nutritional supplement for children that is ready-to-use. See Trimbo col. 6, lns. 1 - 2. Thus, Trimbo would not suggest to one of ordinary skill in the art to make the concentrated solutions of claims 44 - 47. The obviousness rejection of these claims over Trimbo should be withdrawn.

Conclusion

Based on the foregoing, all claims are believed in condition for allowance. An early and favorable action toward that end is earnestly solicited.

Respectfully submitted,

AJAY GUPTA

By: _____

DANIEL A. MONACO
Registration No. 30,480
SEIDEL, GONDA, LAVORGNA
& MONACO, P.C.
Suite 1800, Two Penn Center
Philadelphia, PA 19102
Telephone No.: (215) 568-8383
Facsimile No.: (215) 568-5549

Attorney for Applicant

Ariadne's Thread in the AIPA Labyrinth

FINDING A WINNING PATH THROUGH THE 102(E)/374/PCT MAZE.[1]

MARIA ELISEEVA[2] OF
NUTTER MCCLENNEN &
FISH LLP,
ONE INTERNATIONAL PL.
BOSTON, MA 02110

Changes to 35 U.S.C. §102(e) and 35 U.S.C. §374 by Subtitle E of the American Inventors Protection Act (AIPA) set forth new patentability conditions an applicant for a U.S. patent must satisfy in order to get a patent, as well as new prior art treatment of patent applications published in the U.S. and certain International patent applications (PCT applications). In particular, under the amended section 102(e) a published U.S. patent application becomes a prior art reference against the applicant as of its effective filing date. In a somewhat similar manner the amended §374 makes a published PCT application equivalent to an application filed and published in the U.S. for prior art purposes, if that PCT application designates the U.S. and is published in the English language under 35 U.S.C. §122(b). Since it is very likely that the changes made by the AIPA to §102(e) and §374 will affect all pending files on our dockets, it is important to analyze and understand various possible patent prosecution scenarios created by the amendments which took effect on November 29, 2000. We will call that day E-Day (effective day) in order simplify the discussion.

Under the old (pre-AIPA) §102(e) only a U.S. patent was a reference against the applicant. The date of the U.S. patent as a reference was the patent's effective filing date in the U.S., which was either the U.S. filing date of the earliest national application or the date on which the national stage of a PCT application entering the U.S. fulfilled the requirements 35 U.S.C. §371(1), (2) and (4). Under the pre-AIPA §374 a published PCT application could never have a 102(e) effect in the U.S. A published PCT application could only have a 35 U.S.C. 102(a) or 102(b) effect as of the publication date.

New §102(e) defines its bar to patentability in a situation when

> [t]he invention was described in:
>
> (1) an application for patent published under section 122(b) by another filed in the United States before the invention by the applicant for patent, except that [a PCT application] shall have the effect under this subsection of a national application published under section 122(b) only if the [PCT] application designating the United States was published under Article 21(2)(a) of [PCT] in the English language; or
>
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of [a PCT application].

The language of the new §102(e)(1) and §102(e)(2) essentially defines four possible types of prior art references: published 111(a) applications (U.S. national filings), published PCT applications, published national stage applications, and U.S. patents. In addition, since the applicant whose application was pending on E-Day has an option to request voluntary publication of the application, such voluntarily published applications will become prior art references either as published national 111(a) applications or as published national stage applications. Therefore, in order to understand the effect of one or more prior art references created by the new §102(e), it is important to figure out (1) what the 102(e) effect of a reference is and (2) what that reference is usable against.

There is one more consideration we need to think about before embarking on the analysis of various specific examples of new patent prosecution scenarios created by Subtitle E of the AIPA. Section 4508 of the AIPA sets forth the day (E-Day, November 29, 2000) on which the amendments became effective by providing the following:

> [1] Sections 4502 through 4507, and the amendments made by such sections, shall take effect on date *[Nov. 29, 2000]* ... and shall apply to
>
> -all applications filed under section 111 of title 35... on or after that date, and
>
> -all applications complying with section 371 of title 35...that resulted from international applications filed on or after that date...
>
> [2] The amendments made by sections 4504 [*provisional rights*] and 4505 [*102(e)(1) and (2)*] shall apply to any such application voluntarily published... that is pending on [*Nov. 29, 2000*].
>
> [3] The amendments made by sections 4504 *[provisional rights]* shall also apply to international applications designating the US that are filed on or before *[Nov. 29, 2000]*.

The language of the first sentence of section 4508 seems to be ambiguous as to whether E-Day applies to *references* or *applications being examined*. The view of the Patent Office is that since §102(e) specifies *a condition for patentability*, it should apply to an application being examined regardless of the effective date of a reference being cited against such an application. In other words, applications filed before E-Day are subject to a pre-AIPA set of statutory bars, including pre-AIPA §102(e). Applications filed on or after E-Day are subject to the changes made by the AIPA, including the amended §102(e). Applications filed before E-Day that are voluntarily published are subject to the amended §102(e) with an exception regarding published PCT applications as discussed below.

PRIOR ART EFFECT OF PUBLISHED 111(A) APPLICATIONS.

1. Let's consider the simplest case of a national §111(a) application A filed on January 1, 2001, which is a post-E-Day filing. Application A will be published under 35 U.S.C. §122(b)[3] on July 1, 2002, 18 months after its filing day. According to the amended §102(e)(1), publication P of the application A is now a prior art reference with an effective date for prior art purposes that is earlier than its publication date.

What is the effective date of P? §102(e)(1) says that a reference is "an application for patent published under §122(b) by another *filed* in the United States...". Recall that under the pre-AIPA §102(e) "filed" means that the reference (a U.S. patent) is accorded the earliest effective U.S. filing date[4]. Therefore, by analogy the 102(e)(1) date of the published application P is January 1, 2001, and that published application P can be used against any application filed after January 1, 2001.[5]

2. What if a post-E-Day application A claims the benefit of a provisional application (a 111(b) application) filed before E-Day? For example, a 111(b) application was filed on January 1, 2000. A 111(a) application A is filed on January 1, 2001, claiming priority from the provisional under §119(e), and published on July 1, 2001. What is the effective date of such published application P? Again, analogously to the pre-AIPA §102(e), the 102(e)(1) date of publication P goes all the way back to the earliest effective U.S. filing date, which, in our case, is January 1, 2000, the filing date of the provisional application.[6] Publication P is usable against any application filed on or after E-Day, or against an application filed between January 1, 2000 and E-Day and voluntarily published.[7]

3. Another possible scenario arises when a later-filed 111(a) application claims priority from an earlier pre-E-Day 111(a) application under 35 USC §120 (domestic continuity). For example, suppose the first 111(a) application ("A1") was filed on January 1, 2000 and the second 111(a) application ("A2 ") was filed on January 1, 2002, claiming priority from A1 under §120. A2 eventually becomes a published patent application P on July 1, 2002. Similarly to the previous example, for subject matter in P, which is fully supported by A1, the 102(e)(1) effective prior art date of P is January 1, 2000.[8] P is usable against any application filed on or after E-Day, or against an application filed between January 1, 2000 and E-Day and voluntarily published.

Note that this example is illustrative of what a potent weapon a published patent application can become under the amended §102(e)(1). Although A2 is published only on July 1, 2002, its offensive strength against applications of others goes back 2.5 years to January 1, 2000. Since a continuation application under §120 does not have to be filed within a year of the filing date of a previous application (only mere copendency is required), then it is realistically possible to have a published U.S. application with a 102(e)(1) date against others going 2 or 3 or 4 (or more?) years back, if a series of continuations had been filed from the original 111(a) application.

4. As before the AIPA, no benefit of an earlier filed foreign application is accorded to an application subsequently filed in the U.S.[9] For example, suppose an application F was filed on January 1, 1999, in a foreign country and suppose a 111(a) application ("A1") was filed in the U.S. on December 31, 1999, claiming priority from F under the Paris Convention. Suppose further that on July 1, 2002, a second 111(a) application ("A2") was filed with a priority claim to A1 under 35 USC § 120. A2 is later published to become published application P. Since In re Hilmer continues to be the law governing benefits claimed from foreign applications, the effective 102(e)(1) date of P as a reference is December 31, 1999, and not January 1, 1999. P is usable against any application filed on or after E-Day, or against an application filed between December 31, 1999, and E-Day and voluntarily published.[10]

5. As the last example in this subsection, consider the 102(e) effect of a published 111(a) application claiming the benefit of an earlier filing date of a PCT application. Let's revisit the provisions of law that make such priority claims possible.

Under PCT Article 11 the U.S. is required to treat PCT applications as filed in the U.S. as of their international filing date. Article 64(4), however, provides a reservation to Article 11. Article 64(4) says that if a country (the U.S. in our case) accords its patents a prior art date other than the publication date (as it is in the U.S.), then such a country is allowed to treat PCT applications filed outside of the country as being filed on a date other than the international filing date. Since 35 U.S.C. §102(e) accords U.S. patents the prior art date as of the earliest effective filing date in the U.S., the U.S. is allowed to treat PCT applications filed outside the U.S. as being filed on a date other than the international filing date for prior art purposes. That reservation is implemented in 35 U.S.C. §363.

35 U.S.C §365(c) says that a national 111(a) application and a PCT application can claim priority from each other in accordance with §120. Section 120 provides that a later-filed national 111(a) application is treated as if filed on the date of an earlier filed national application or a PCT filed under §363. Section 363 provides that a PCT application is treated as a 111(a) national application except as provided in §102(e). The amended §102(e)(1) says that a PCT application is treated as a national application when the PCT: (1) designates the US, (2) is published in English, and (3) is published under PCT Art. 21(2)(a).[11] For the purposes of this discussion we will call a PCT application designating the U.S. and published in English under Art. 21(2)(a) a "compliant PCT". Therefore, under the amended §102(e)(1) only a compliant PCT will be treated as filed in the U.S. as of its international filing date.[12]

Back to the promised example. Assume that a provisional (§111(b)) application was filed on January 1, 1999 and that a PCT application designating the U.S. was filed on December 31, 1999. A 111(a) application ("A") claiming the benefit of the filing date of the PCT application under §365(c) is filed after E-Day on July 1, 2001. The 111(a) application is published on August 1, 2001 ("P"). What is the 102(e)(1) date of P?

Publication P has a July 1, 2001, 102(e)(1) date if the PCT is not published in English under Art. 21(2)(a) and is, therefore, non-compliant. Its 102(e)(1) date is the filing date of application A. If, on the other hand, the PCT is a compliant PCT, then the 102(e)(1) date of P is January 1, 1999. The reference is usable against any application filed on or after E-Day, and against any application filed between January 1, 1999, and E-Day, and voluntarily published.[13]

PRIOR ART EFFECT OF PUBLISHED PCT APPLICATIONS.

While the amended §120(e) creates new patentability condition for an application under examination, the amended §374 creates a new category of prior art references that have an effective date earlier than their publication date, namely published PCT applications. Published PCT applications have, of course, always been references against U.S. applications. The AIPA introduces a fundamental change in the effective date of such a reference. Before the AIPA a published PCT application was only a 102(a) or 102(b) reference against a pending application *as of the date of publication*, but was never a 102(e) reference. The amended §374 now provides that

> [T]he publication under [PCT] of an international application designating the United States shall confer the same rights and shall have the same

> effect under this title [35 USC] as an application for patent published under section 122(b), except as provided in sections 102(e) and 154(b) of this title.

It follows from the above language and the language of §102(e)(1) that if a PCT application designates the U.S. and is published in English under PCT article 21(2)(a), such a PCT is equivalent to a national application for 102(e) purposes. Therefore, the effective date of a published PCT application under §102(e)(1) is the international filing date of that PCT. A couple of examples are illustrative of the changes provided by the amended §374.

1. A compliant PCT application filed on January 1, 2001, and published on July 1, 2002, will be treated as a national application published under §122(b) and filed on the international filing date. The application's 102(e)(1) prior art date is January 1, 2001.[14]

2. Suppose a compliant PCT application filed on January 1, 2001, claims priority from a previously filed 111(a) or 111(b) application filed on January 1, 2000. The PCT application is published on July 1, 2001, with the 102(e)(1) date of January 1, 2000. Note that instead of the day of publication, July 1, 2001, the published compliant PCT application now has a more potent 102(e) prior art date of January 1, 2000. The published PCT is usable against applications filed on or after E-Day.

Can a published PCT application be a 102(e)(1) reference against a voluntarily published application? The language of the second sentence of section 4508 of the AIPA suggests that the answer is "no". That language says that a voluntarily published application will enjoy the benefit of the provisional rights and will be subject to the new patentability condition of section 102(e). The second sentence of section 4508 is silent with respect to the voluntary published applications being subject to the new type of prior art (published compliant PCT applications). Therefore, it seems that a published PCT does not have a 102(e) against voluntarily published applications pending before E-Day.[15]

PUBLISHED NATIONAL STAGE APPLICATIONS AS PRIOR ART

Why should we care about the prior art effect of a published national stage (NS) application? The PCT application of which it is the national stage will already have been published and, if that PCT is a compliant PCT, the publication will have its own 102(e) date probably much sooner than the publication of the subsequent NS application.

There is at least one reason to pay attention to the 102(e) effect of published NS applications: since a published PCT most likely can not be used against voluntarily published applications, it might happen that the earliest 102(e) date will become available when the NS application is published. This is illustrated in the following scenario.

1. Suppose a compliant PCT is filed on January 1, 2001 and is published in English on July 1, 2002, entering the US national stage ("NS") on July 1, 2003. Publication of the NS application under §122(b) occurs on August 1, 2003. The 102(e)(1) date of the published NS application will be January 1, 2001.[16]

2. Let's change the facts and assume that the PCT was filed in non-English and published in non-English, therefore becoming a non-compliant PCT for 102(e)(1) purposes. The published NS application will have no 102(e)(1) date (and the same may be said for the published PCT application). Please note that a non-compliant PCT is not equivalent to a national U.S. filing. Moreover, since a national stage application of a PCT is not a national 111(a) application, but is legally the same as the PCT application, then under the new §102(e)(1) the national stage application has no filing date in the U.S. other than the international filing date of the PCT. Note also that the §371 fulfillment date[17] has no significance under the amended §102(e). Therefore, a published NS application stemming from a non-compliant PCT has no filing date in the U.S and no prior art effect under the new §102(e)(1).[18] It will, however, be a reference under §102(a) and §102(b).

PATENTS AS PRIOR ART

A similar question can be asked: why do we care about U.S. patents being 102 (e) prior art references at all, if every application will be now published and become a reference before the patent is issued?

One of the answers is that the pre-AIPA §102(e) will still apply to the applications pending before E-Day that will not be voluntarily published. Otherwise, a patent will have the same old §102(e) and new §102(e)(2) dates if it matures from one or more domestic applications.[19]

Another answer is that the 102(e) analysis of an issued patent changes dramatically (due to the AIPA) if the patent matured from an application stemming from a PCT application.

1. Consider, for example, a complaint PCT filed on January 1, 2000 and a subsequent 111(a) application claiming priority from the PCT under §365(c) filed on January 1, 2001. A patent maturing from the 111(a) application will have a 102(e)(2) prior art date of January 1, 2001, since §102(e)(2) says that "a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of [a PCT application]". Therefore, no matter whether the PCT is compliant or not, only the filing date of a national 111(a) U.S. application will accord the subsequent patent its 102(e)(2) date.[20] Who cares, the question may be asked again. The compliant PCT application will have been published, so it will provide the 102(e) date for the subject matter of the issued patent. The answer is that, as noted above, a voluntarily published application is not subject to the 102(e) effect of a published PCT. Thus, if a competitor's application is voluntarily published and later issues as a patent, it may turn out later, for example, in litigation, that another's patent's 102(e) date is important for invalidating the competitor's patent.

2. There can be a scenario when the 102(e)(2) date of a patent will become completely unavailable for applications filed after E-Day or voluntarily published. For example, suppose a compliant PCT filed on October 31, 1999, enters the US national stage (NS) and fulfills the requirements of §371(1),(2), and (4) on May 20, 2000 (before E-Day). According to the language of amended §102(e)(2), the patent issuing on August 1, 2001, will have no 102(e)(2) date for applications filed after E-Day or pending on E-Day and voluntarily published. For applications filed between May 20, 2000 and E-day which are not voluntarily published, the old 102(e) date will be May 20, 2000. Note that for the new §102(e)(2) the date of fulfillment of the

requirements of §371 for a NS application is completely irrelevant.[21]

EFFECT OF VOLUNTARY PUBLICATION

As noted above, 111(a) applications filed before E-Day and pending on E-Day, as well as National Stage applications resulting from PCT applications filed before the E-Day, can request voluntary publication. As a result, the voluntarily published application will be subject to the new patentability conditions under §102(e). Let's consider the effect of voluntary publication on just a couple of possible prosecution scenarios.

1. Suppose the Examiner rejects the claims in my application under old §102(e) over a patent to X. Suppose further X's patent matured from a national stage (NS) of a PCT application published in German. The effective date of the NS asserted by the Examiner against my application is the date when X satisfied the requirements of §371(1), (2), (4), which in our example is earlier my date of invention. If I voluntarily publish my application, then it will become subject to patentability under new § 102(e)(2), as provided in section 4508 of the AIPA. Section 102(e)(2) denies 102(e) prior art date to any issued patent coming from a PCT application. Therefore, the rejection over the patent to X will be eliminated. Will a published PCT application of X be a reference against my application? The answer is "no", because voluntarily published applications are most likely not subject to prior art effect of published PCT applications. Importantly, the mere act of requesting voluntary publication may change an unpatentable application into a patentable application.

2. Conversely, voluntary publication of an application will make the application subject to new §102(e). If the application contained some claims which were allowable under old §102(e), it may turn out that such claims are not allowable because of the 102(e)(1) prior art effect of published 111(a) or NS applications stemming from compliant PCT applications. Therefore, while voluntary publication offers an applicant the potential benefit of pre-issuance damages, there is a risk that the allowable claims will be held unpatentable over the wide range of prior art permitted by the new §102(e).

QUESTIONS TO THINK ABOUT

After having worked through the numerous prosecution scenarios described above, the question arises: are they really relevant to a patent practitioner's everyday practice[22]? After all, in 5-6 years there probably will be no need to think about voluntarily published applications and applications with pre-E-Day effective filing dates, since the applications' earliest filing dates will be post-E-Day anyway.

The answer to that question is "yes", it is necessary to think about all possible implications of the amendments created by Subtitle E of the AIPA now for at least two reasons. One reason is that the knowledge of new patentability criteria and the new kinds of prior art will help us devise the best strategy of obtaining strong patents for our clients. The other reason is that a patent can be litigated, so it is better to be aware of the new 102(e) applicable prior art now than to become aware of it with the help of an adversary in litigation.

What are the considerations we should think of?

One of them relates to voluntary publications: should I or should I not? On the one hand, voluntary publication makes the future patentee entitled to the pre-grant damages. On the other hand the new §102(e) patentability conditions will apply together with the new types of prior art created by §102(e) and §374.

Another consideration relates to the question of whether I should try to make a PCT application compliant with the conditions of §102(e)(1). It seems that I probably should, but there can be a number of business reasons related to the fact that the client would prefer to file PCT applications abroad and publish them in a foreign language. For such a client it probably would be advisable to employ the time-honored strategy of parallel U.S. filings in order to get the client the best 102(e)(1) date in the U.S. even though the client's non-compliant PCTs do not provide for good 102(e)(1) dates.

WHAT'S NEXT?

As always, it depends. Subtitle E of the AIPA became effective on November 29, 2000, and is now the law. Nevertheless, it is also important to keep in mind that a bill pending in Congress could potentially change the language of 35 USC §102(e) and Section 4508 of the AIPA yet again. This bill, if enacted into law in its present form, would change the bar language of §102(e) to the following:

> the invention was described in (1) an application for patent, published under section 122(b), by another in the U.S. before the invention by the applicant...or (2) a patent granted on an application for patent filed by another in the U.S..., except that a [PCT application] shall have the effects for the purposes of this subsection of an application filed in the U.S. if and only if the [PCT application] designated the U.S. and was published under PCT Article 21(2) in English.

How will the changes, if enacted in the present form, affect various prosecution scenarios? Perhaps it is a subject for another journey through a different maze, which can be described in a different article. IPT

ENDNOTES

1. The author is deeply grateful to Stephen G. Kunin, Deputy Commissioner for Patent Examination Policy of the United States Patent & Trademark Office, for his helpful examples and insights in preparation of this material. Any mistakes found in this article should, of course, be attributed only to the author.
2. The author can be reached by e-mail at me@nutter.com or maria@patentbar.com.
3. §122(b) covers both 18-month publications and early publications, if requested by the Applicant.
4. Alexander Milburn Co. v. Davis-Bournonville Co., 270 U.S. 390 (1968).
5. Since it is probably quite difficult to work through this and later scenarios without having a graphical representation of the dates and events, please refer to the slides posted at http://www.patentbar.com/aipa, which you may wish to view while reading the article. This scenario is depicted at http://www.patentbar.com/aipa/s5.jpg
6. It is, of course, understood that the earlier application (the provisional in this example) should fully support the relied-upon subject matter of the 111(a) application.
7. http://www.patentbar.com/aipa/s6.jpg
8. http://www.patentbar.com/aipa/s7.jpg
9. In re Hilmer, 149 USPQ 480 (CCPA 1966)).
10. http://www.patentbar.com/aipa/s9.jpg
11. Note that PCT Art. 21(2)(a) provides for a default 18 month publication. It seems that if an applicant requests early publication (for whatever reason that might be), such publication will fall under Art. 21(2)(b).
12. http://www.patentbar.com/aipa/s10.jpg
13. http://www.patentbar.com/aipa/s11.jpg
14. http://www.patentbar.com/aipa/s13.jpg
15. http://www.patentbar.com/aipa/s14.jpg
16. http://www.patentbar.com/aipa/s15.jpg
17. By this we mean the date upon which §371 (1), (2) and (4) were fulfilled, a date which mattered under the old §102(e), but which does not make any difference under the new §102(e).
18. http://www.patentbar.com/aipa/s16.jpg
19. http://www.patentbar.com/aipa/s17.jpg
20. http://www.patentbar.com/aipa/s18.jpg
21. http://www.patentbar.com/aipa/s19.jpg
22. If you would like to work through several more complex prosecution scenarios, please refer to http://www.patentbar.com/aipa/s20.jpg, http://www.patentbar.com/aipa/s21.jpg, http://www.patentbar.com/aipa/s24.jpg, http://www.patentbar.com/aipa/s25.jpg
23. H.R. 4870,Technical Corrections to Patent, Copyright and Trademark Laws